International Academy of Compounding Pharmacists

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July 18, 2000

Dr. Jane E. Henney
Commissioner (HF-1)
Food and Drug Administration
5600 Fisher's Lane, Room 1471
Rockville, Maryland 20857-001

Re: Docket Number 98D-0272

Dear Dr. Henney:

The following letter is being submitted by the International Academy of Compounding Pharmacists (IACP) in response to the Food and Drug Administration's (FDA) brief appealing the decision by the United States District Court for the District of Nevada in Western States Med. Ctr., v. Shalala, 69 F. Supp. 1288 (D. Nev. Sept. 16, 1999). IACP objects to the tenor of the arguments proffered in the brief and to FDA's use of the appeals process as a forum in which to wage an unrelenting attack on the practice of pharmacy compounding.

FDA's basic contention in the brief is that pharmacy compounding is bad. Rather than aggressively arguing the merits of its case under the First Amendment with respect to the advertising provisions, FDA resorts to a repeated attack on the practice of pharmacy compounding and why it should be minimized.

FDA's anti-compounding bias pervades this brief, contending that "[t]his case is about 'compounding' prescription drugs."[1] FDA bases its defense of the statute on assaulting the practice of compounding. However, the issue is not the desirability of

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1 Brief For Appellant at 2, Western States Med. Ctr., v. Shalala, 69 F. Supp. 1288 (D. Nev. Sept. 16, 1999) No.99-17424 [hereinafter FDA Brief].

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compounding — it is about the constitutionality of the discrete advertising restrictions encompassed in Section 503A(c).

The core of FDA's argument is that compounding is not safe and should be limited. FDA argues that Congress included the advertising and promotion provisions as a mechanism to reduce the amount of pharmacy compounding conducted. (FDA Brief at 23). FDA cites no authority to sustain this conclusion. FDA also states "[i]f the district court's ruling in this case were to stand, it would permit pharmacy drug manufacturers to induce customers to purchase their products for uses that have not been determined to be safe and effective." (FDA Brief at 20). This ignores Congress' decision to exempt compounded drugs from the new drug requirements with respect to safety and efficacy. It also suggests that the mere act of advertising the ability to compound a specific drug would induce physicians to abandon all medical judgment and simply write prescriptions for that drug.

The brief is replete with statements contending that pharmacy compounding — in any amount — is unsafe. FDA goes so far as to insinuate that the risk associated with the use of compounded drugs rises to level of risk associated with the use of unapproved unconventional therapies. (FDA Brief at 34). In addition, FDA states that '[b]y fostering demand for [a] compounded product . . . more people are exposed to the risks inherent in unapproved drugs." (FDA brief at 47). Thus, even when drugs are compounded in accordance with criteria outlined section 503A, FDA believes that they represent an "inherent" danger to patients.

FDA also appears to believe that the pharmacy-physician-patient triad does not exist if the pharmacist advertises the ability to compound a drug. This paternalistic view

of the medical interaction of patients, physicians and pharmacists fails to recognize the professional capacity of pharmacists and the sophistication of physicians.

IACP does not suggest FDA should not defend the advertising provision of § 503A. FDA is entitled to vigorously support the constitutionality of the provision. However, in its brief, FDA constantly denigrates compounding, portraying it as a last-ditch option that is appropriate only in small quantities, because "a limited number of sales cannot pose a threat to a significant number of people." Brief at 28. FDA's philosophy is that compounding is dangerous, and should be done only sparingly. Put simply, FDA defends the advertising restriction by arguing that compounding — a congressionally sancted action — is undesirable. On behalf of its 1500 members and the tens of thousands of patients they serve, IACP disagrees with this assessment.

FDA's anti-compounding attitude is not confined to the brief. The recent "Concept Paper" on demonstrably difficult products also treats compounded drugs as second class citizens by drawing distinctions based on their lack of FDA approval. Given that Congress has authorized compounding, FDA should treat compounded drugs as a legal alternative — not an inferior — legally-sanctioned source of prescription drugs.

FDA's brief is essentially little more than a renewal of it lobbying efforts against the enactment of section 503A. Congress has spoken, and pharmacy compounding, within the framework of § 503A, is legal. It is time for FDA to drop its adversarial approach toward compounding, and help physicians, pharmacists and patients maximize the benefits that can be gained through the practice of pharmacy compounding. As it moves forward to implement § 503A, FDA should abandon the underlying premise that compounding is bad and a practice to be discouraged.

Sincerely

Shelly Capps

Executive Director